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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:) : Examiner: Yevgeny Valenrod
JONATHAN D. BLOOM ET AL.) : Group Art Unit: 1621
Application No.: 10/682,647)
Filed: October 8, 2003)
For: ANTHRANILIC ACID DERIVATIVES USEFUL IN TREATING INFECTION WITH HEPATITIS C VIRUS	·) :)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132 OF JONATHAN D. BLOOM, Ph.D.

Sir:

I, JONATHAN D. BLOOM, declares and says that:

- 1. I am one of the inventors of the subject matter described and claimed in the above-identified application. I am familiar with the prosecution history of the present application, including the current rejection of claims 11-14, 17 and 18 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Bierer et al. (U.S. 5,741,926) ("Bierer").
- 2. In my opinion, Formula III of Bierer defines a broad genus that provides for numerous possible substituents at positions 2, 3, 4, 5, and 6 of the phenyl ring (R₁-R₅, respectively). The disclosure of Bierer fails to recognize the important notable features of

the present invention. My opinion is based upon both a thorough reading of Bierer and my general knowledge of the art at the time the invention was made.

- 3. In particular, Bierer does not teach having the W/Y substituent shown in claims 11 and 17 of the present invention at the ortho position (position 2). Nor does Bierer teach limiting the possible substituents at that position to COOH or 5-tetrazolyl.
- 4. I requested the performance of the experiments yielding the data presented in Table 1 below.

TABLE 1

<u>Compound</u>	IC ₅₀ for HCV Polymerase
CI COOH	1.6 μΜ
CI COOH	> 33 µM
CI O H	> 29 µM
CI OCH,	> 31 µM

- 5. The data presented in Table 1 demonstrate that both the choice of substituent, as well as its placement in the ortho position, unexpectedly affect activity against HCV polymerase. Specifically, placing a COOH group at the ortho position provides unexpectedly superior activity as compared to both the meta and para positions.
- 6. In conclusion, it is my opinion that Bierer et al. (U.S. 5,741,926) does not make the present invention obvious such that a review of Bierer would motivate one skilled in the art to formulate the claimed compounds and pharmaceutical compositions thereof.

I declare further that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Subscribed this 11th day of May, 2007.

JONATHAN D. BLOOM, Ph.D.